

20720-95585

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Eugenio A. Cefali\*

Application No. : 08/962,027 Confirmation No. :

Filed : October 31, 1997

For : INTERMEDIATE RELEASE NICOTINIC ACID  
COMPOSITIONS FOR TREATING HYPERLIPIDEMIA  
HAVING UNIQUE CMAX, TMAX AND AUC  
BIOPHARMACEUTICAL CHARACTERISTICS

Group : 1615

Examiner : Robert M. Joynes

Hon. Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

30  
7/9/03  
RECEIVED  
TECH CENTER 1600/2900  
MAY 05 2003  
TECH CENTER 1600/2900

TRANSMITTAL LETTER

Sir:

Transmitted herewith is:

[x] An Information Disclosure Statement in the  
above-identified application; and [X] Form PTO-1449 (in  
duplicate) with copies of the documents cited therein.


\* The inventor on file for this application is Eugenio A. Cefali. A Petition to Correct Inventorship under 37 C.F.R. § 1.48(a) to add David J. Bova as a co-inventor was filed on January 16, 2003 and is currently pending.

Applicant notes that a Petition to Revive Application, a Petition to Withdraw from Issue, a Request for Continued Examination; a Request to Correct Inventorship; a Preliminary Amendment; and a Request to Perfect Priority Claim were filed in the above-identified application on January 16, 2003. An April 11, 2003 Patent Office notification has indicated that the Petition to Revive Application and Petition to Withdraw from Issue have been granted and the application was being returned to the Technology Center 1615.

In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge the payment of any fee in connection with this Information Disclosure Statement to Deposit Account No. 50-2543 (Kos). A duplicate copy of this transmittal letter is enclosed.

Respectfully submitted,

5/2/03  
Date

  
\_\_\_\_\_  
Karen U. Messick (Reg. No. 46,256)  
Attorney for Applicant  
c/o Kos Pharmaceuticals, Inc.  
1001 Brickell Bay Drive  
25th Floor  
Miami, Florida 33131  
Tel.: (305) 523-3643

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Eugenio A. Cefali\*  
Application No. : 08/962,027 Confirmation No. :  
Filed : October 31, 1997  
For : INTERMEDIATE RELEASE NICOTINIC ACID  
COMPOSITIONS FOR TREATING HYPERLIPIDEMIA  
HAVING UNIQUE CMAX, TMAX AND AUC  
BIOPHARMACEUTICAL CHARACTERISTICS  
Group : 1615  
Examiner : Robert M. Joynes

Hon. Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.56 AND 1.97(b)

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b),  
applicant, through his representatives, makes of record the  
following documents, copies of which are enclosed herewith:†

---

\* The inventor on file for this application is Eugenio A. Cefali. A Petition to Correct Inventorship under 37 C.F.R. § 1.48(a) to add David J. Bova as a co-inventor was filed on January 16, 2003 and is currently pending.

† For the convenience of the Examiner, a completed Form PTO-1449 listing these documents is attached hereto in duplicate.

RECEIVED  
TECH CENTER 1600/2900  
03 MAY -5 PM 12:58

RECEIVED  
MAY 05 2003  
TECH CENTER 1600/2900

United States Patents

Fields et al.	Re. 29,652	05/30/1978
Scherm et al.	Re. 32,581	01/19/1998
Woodward et al.	2,510,164	06/06/1950
Clymer et al.	2,540,979	02/06/1951
Buckwalter	2,749,274	06/05/1956
Sahyun	2,798,837	07/09/1957
Robinson	2,798,838	07/09/1957
Robinson et al.	2,805,977	09/10/1957
Kennon et al.	2,851,453	09/09/1958
Cooper et al.	2,857,313	10/21/1958
Klioze et al.	2,887,436	05/19/1959
Schuyler	2,957,804	10/25/1960
Costello	3,062,720	11/06/1962
Christenson et al.	3,065,143	11/20/1962
Harbit	3,108,046	10/22/1963
Siegel et al.	3,116,204	12/31/1963
Sheth et al.	3,134,719	05/26/1964
Debay et al.	3,143,469	08/04/1964
Playfair	3,147,187	09/01/1964
Eisen	3,193,461	07/06/1965
Blank et al.	3,210,413	10/05/1965
Nakano et al.	3,272,832	09/13/1966
Krause et al.	3,336,200	08/15/1967
Nürnberg	3,424,842	01/28/1969
Fossel	3,495,011	02/10/1970
Christenson et al.	3,590,117	06/29/1971
Kariya et al.	3,626,071	12/07/1971
Nakamota et al.	3,629,393	12/21/1971
Waring	3,629,453	12/21/1971
Poole	3,634,584	01/11/1972
Barnhart	3,639,636	02/01/1972
Miller	3,709,991	01/09/1973
Thiffault	3,721,735	03/20/1973
Nakamoto et al.	3,773,920	11/20/1973
Douglas et al.	3,795,691	03/05/1974
Mikite et al.	3,806,601	04/23/1974
Winitz	3,849,554	11/19/1974
Weigand	3,859,437	01/07/1975
Barnhart et al.	3,862,332	01/21/1975
Albright et al.	3,868,416	02/25/1975
Lowey et al.	3,870,790	03/11/1975
Fields et al.	3,923,972	12/02/1975
Albright et al.	3,924,001	12/02/1975
Kummer et al.	3,930,017	12/30/1975
Davidson	3,951,821	04/20/1976
Sugimoto	3,957,976	05/18/1976

Coulston et al.	3,959,492	05/25/1976
Bloch et al.	3,965,255	06/22/1976
Theeuwes	3,977,404	08/31/1976
Broughton et al.	3,987,160	10/19/1976
Kleemann et al.	3,992,536	11/16/1976
Möller et al.	4,002,641	01/11/1977
Theeuwes et al.	4,008,719	02/22/1977
Galantay et al.	4,011,339	03/08/1977
Theeuwes et al.	4,014,334	03/29/1977
Heller et al.	4,014,987	03/29/1977
Voorhees	4,034,087	07/05/1977
Theeuwes	4,034,758	07/12/1977
Theeuwes et al.	4,058,122	11/15/1977
Ferutti et al.	4,067,876	01/10/1978
Theeuwes et al.	4,077,407	03/07/1978
Kondo et al.	4,102,806	07/25/1978
Fields et al.	4,115,550	09/19/1978
Theeuwes et al.	4,116,241	09/26/1978
Fields et al.	4,117,111	09/26/1978
Sheth et al.	4,126,672	11/21/1978
Sheth et al.	4,140,755	02/20/1979
Ayer et al.	4,160,020	07/03/1979
Theeuwes	4,160,452	07/10/1979
Ferruti	4,166,902	09/04/1979
Sheth et al.	4,167,558	09/11/1979
Scallen et al.	4,169,944	10/02/1979
Diamond et al.	4,178,387	12/11/1979
Heller et al.	4,180,064	12/25/1979
Thiele et al.	4,182,902	01/08/1980
Theeuwes	4,203,439	05/20/1980
Shepherd	4,205,085	05/27/1980
Shepherd	4,211,783	07/08/1980
Schor	4,226,849	10/07/1980
Shepherd	4,230,878	10/28/1980
Howard	4,237,118	12/02/1980
DeNeale et al.	4,248,857	02/03/1981
Robbins et al.	4,251,519	02/17/1981
Cavazza	4,255,449	03/10/1981
Theeuwes	4,256,108	03/17/1981
Lowey	4,259,314	03/31/1981
Ogawa et al.	4,261,970	04/14/1981
Cavazza	4,268,524	05/19/1981
Gatzen et al.	4,272,548	06/09/1981
Engel et al.	4,279,898	07/21/1981
Vilani	4,282,233	08/04/1981
Frank et al.	4,283,382	08/11/1981
Hoefle	4,285,951	08/25/1981
Mulinos	4,291,030	09/22/1981

Shepherd	4,305,959	12/15/1981
Dunn et al.	4,308,251	12/29/1981
DeNeale et al.	4,309,404	01/05/1982
Shepherd	4,310,545	01/12/1982
Shepherd	4,318,914	03/09/1982
Swanson et al.	4,326,525	04/27/1982
Shepherd	4,348,399	09/07/1982
Hess et al.	4,353,887	10/12/1982
Schor	4,357,469	11/02/1982
Stricker et al.	4,361,546	11/30/1982
Cerami	4,362,711	12/07/1982
Gruber et al.	4,367,217	01/04/1983
<sup>†</sup> Schor et al.	4,369,172	01/18/1983
Dunn	4,375,468	03/01/1983
Shepherd	4,382,143	05/03/1983
<sup>†</sup> Schor et al.	4,389,393	06/21/1983
Hata et al.	4,428,951	01/31/1984
Zeitoun et al.	4,432,966	02/21/1984
Shepherd	4,440,940	04/03/1984
Kent	4,452,775	06/05/1984
Iida et al.	4,454,108	06/12/1984
McFarlane et al.	4,455,298	06/19/1984
Porter	4,457,907	07/03/1984
Dunn	4,461,759	07/24/1984
David et al.	4,465,660	08/14/1984
Hooper	4,472,436	09/18/1984
Hercelin et al.	4,478,819	10/23/1984
Shepherd	4,485,105	11/27/1984
<sup>†**</sup> Jain et al.	4,505,890	03/19/1985
Dunn	4,522,804	06/11/1985
Dunn et al.	4,525,345	06/25/1985
Powell et al.	4,539,198	09/03/1985
Davis et al.	4,540,566	09/10/1985
Zierenberg et al.	4,547,359	10/15/1985
Hsiao et al.	4,556,678	12/03/1985
Herschler	4,568,547	02/04/1986
Hsiao	4,571,333	02/18/1986

---

<sup>†</sup> This symbol indicates documents cited by Barr Laboratories in connection with litigation between Kos Pharmaceuticals and Barr Laboratories currently pending in the Southern District of New York. Kos Pharmaceuticals is the assignee of record of the pending application.

<sup>\*\*</sup> This symbol indicates documents cited to the Examiner for the first time.

Guittard et al.	4,576,604	03/18/1986
Burger et al.	4,603,142	07/29/1986
Schmidt et al.	4,605,666	08/12/1986
'Jain et al.	4,610,870	09/09/1986
Sasaki et al.	4,624,950	11/25/1986
Hanna et al.	4,657,757	04/14/1987
Guittard et al.	4,673,405	06/16/1987
Alderman et al.	4,678,516	07/07/1987
Lowey	4,680,323	07/14/1987
Bhutani	4,684,516	08/04/1987
Powell et al.	4,690,824	09/01/1987
Ukigaya et al.	4,692,337	09/08/1987
Uemura et al.	4,695,467	09/22/1987
Hanna et al.	4,695,591	09/22/1987
Maruyama et al.	4,695,910	09/22/1987
Sander et al.	4,696,762	09/29/1987
Alderman	4,704,285	11/03/1987
Cohen et al.	4,708,834	11/24/1987
Finnan et al.	4,710,519	12/01/1987
Ando et al.	4,713,245	12/15/1987
Makino et al.	4,729,895	03/08/1988
Alderman	4,734,285	03/29/1988
Klimchak et al.	4,744,907	05/17/1988
Shaw et al.	4,747,881	05/31/1988
Rotman	4,749,575	06/07/1988
Briggs et al.	4,752,479	06/21/1988
Oren et al.	4,753,801	06/28/1988
Makino et al.	4,755,544	07/05/1988
'Drost et al.	4,756,911	07/12/1988
Scherm et al.	4,758,581	07/19/1988
Buntin et al.	4,759,923	07/26/1988
Grimberg	4,764,374	08/16/1988
Mookerjea et al.	4,775,483	10/04/1988
Lowey	4,775,535	10/04/1988
Toda et al.	4,777,042	10/11/1988
Ventouras	4,784,858	11/15/1988
Khan et al.	4,789,549	12/06/1988
Howard et al.	4,792,452	12/20/1988
Elben et al.	4,792,554	12/20/1988
Takahasi et al.	4,794,115	12/27/1988
Gaylord et al.	4,795,327	01/03/1989
Cohen et al.	4,795,642	01/03/1989
Zentner	4,795,644	01/03/1989
Hsiao et al.	4,803,079	02/07/1989
Falk et al.	4,803,081	02/07/1989
Rossi et al.	4,812,316	03/14/1989
Zentner	4,814,183	03/21/1989
Ghebre-Sellassie et al.	4,814,354	03/21/1989

Day et al.	4,824,672	04/25/1989
Shah et al.	4,824,677	04/25/1989
Elger et al.	4,828,836	05/09/1989
Finnan	4,830,859	05/16/1989
Martani et al.	4,834,965	05/30/1989
Elger et al.	4,834,985	05/30/1989
Ortega	4,837,032	06/06/1989
Colombo et al.	4,839,177	06/13/1989
Nishimura et al.	4,842,863	06/27/1989
Elger et al.	4,844,907	07/04/1989
Gaylord et al.	4,849,229	07/18/1989
Urquhart et al.	4,851,232	07/25/1989
Khan et al.	4,851,233	07/25/1989
Lowey	4,855,143	08/08/1989
Khanna et al.	4,857,336	08/15/1989
Izydore et al.	4,866,058	09/12/1989
Edgren et al.	4,871,548	10/03/1989
Jang	4,882,167	11/21/1989
Ventouras	4,886,669	12/12/1989
Rotini et al.	4,888,178	12/19/1989
Ohm et al.	4,892,741	01/09/1990
Kuhrts	4,911,917	03/27/1990
Ayer et al.	4,915,952	04/10/1990
Nestler et al.	4,920,115	04/24/1990
Beyer, Jr.	4,920,123	04/24/1990
Boeckh et al.	4,925,905	05/15/1990
Ahrens	4,935,246	06/19/1990
Sparks et al.	4,940,588	07/10/1990
Ragnarsson et al.	4,942,040	07/17/1990
Partain, III et al.	4,946,870	08/07/1990
Izydore et al.	4,946,963	08/07/1990
Yang et al.	4,950,689	08/21/1990
Sparks et al.	4,952,402	08/28/1990
Möller et al.	4,959,478	09/25/1990
Ecanow	4,963,367	10/16/1990
Kuhrts	4,965,252	10/23/1990
Michelucci et al.	4,966,768	10/30/1990
Oren et al.	4,968,508	11/06/1990
Frisbee	4,970,081	11/13/1990
Chiang et al.	4,973,468	11/27/1990
Mulligan et al.	4,973,469	11/27/1990
Gaylord et al.	4,983,398	01/08/1991
Cho et al.	4,990,535	02/05/1991
Khanna	4,992,278	02/12/1991
Sablotsky	4,994,267	02/19/1991
Baichwal et al.	4,994,276	02/19/1991
Sinnreich	4,996,058	02/26/1991
Alberts et al.	4,997,658	03/05/1991



Berger et al.	4,999,380	03/12/1991
Agrawala	5,002,774	03/26/1991
Lui	5,009,895	04/23/1991
Lee	5,010,105	04/23/1991
Catt et al.	5,011,947	04/30/1991
Mulligan et al.	5,015,479	05/14/1991
Kuhrts	5,023,245	06/11/1991
Miura et al.	5,025,012	06/18/1991
Trivedi	5,030,653	07/09/1991
Dansereau et al.	5,032,406	07/16/1991
Izydore et al.	5,034,528	07/23/1991
Meyer	5,039,341	08/13/1991
Calanchi et al.	5,047,248	09/10/1991
Lee et al.	5,049,696	09/17/1991
Kuhrts	5,096,714	03/17/1992
Cho et al.	5,100,675	03/31/1992
Beyer, Jr.	5,110,817	05/05/1992
Sit et al.	5,110,940	05/05/1992
Broadus	5,116,610	05/26/1992
Evenstad et al.	5,126,145	06/30/1992
Mulligan et al.	5,128,142	07/07/1992
Pan et al.	5,130,333	07/14/1992
Sournac et al.	5,132,116	07/21/1992
Paradisiss et al.	5,133,974	07/28/1992
Gakic et al.	5,145,678	09/08/1992
Muhammad et al.	5,167,964	12/01/1992
Dennis et al.	5,169,638	12/08/1992
Baichwal et al.	5,169,639	12/08/1992
France et al.	5,169,640	12/08/1992
Takemori et al.	5,171,570	12/15/1992
Asami et al.	5,178,854	01/12/1993
Helms et al.	5,182,298	01/26/1993
Pearmain	5,188,839	02/23/1993
Commons et al.	5,190,940	03/02/1993
Pan et al.	5,190,970	03/02/1993
Bertolini et al.	5,196,440	03/23/1993
Akkerboom et al.	5,211,958	05/18/1993
Bar-Shalom et al.	5,213,808	05/25/1993
Chiang	5,256,689	10/26/1993
Berger et al.	5,258,401	11/02/1993
Dennick	5,260,305	11/09/1993
Govil et al.	5,262,165	11/16/1993
Joshua et al.	5,262,435	11/16/1993
Graille et al.	5,264,226	11/23/1993
O'Neill et al.	5,268,181	12/07/1993
Dawson et al.	5,278,067	01/11/1994
Soyka et al.	5,286,736	02/15/1994
Kwan et al.	5,314,697	05/24/1994

### FOREIGN PATENT PUBLICATIONS

603,690	Canada	08/16/1960
0 109 320	EP	05/23/1984
0 126 453	EP	11/28/1984
0 349 235 A2	EP	01/03/1990
0 577 504 A1	EP	01/05/1994
1,302,362	France	07/23/1962
40-2053	Japan	02/03/1965
46-18151	Japan	05/20/1971
55-049312	Japan	09/04/1980
2 141 338	UK	12/19/1984
2 154 874	UK	09/18/1985
WO84/00104	PCT	01/19/1984

### OTHER DOCUMENTS

English language translation of Abstract of Japanese Patent No. JP63310827 A 881219 Derwent DW8905 (1988).

English language translation of Abstract of Japanese Patent No. JP5221854 A 930831 Derwent DW9339 A61K9/22 (1993).

Slow Niacin Advertisement, *Am. Druggist*, 141-142 (1988).

Regulatory Letter to Upsher-Smith Laboratories (Jun. 6, 1988).

<sup>†</sup> "Issues in Cholesterol Management: Reappraisal of Niacin," (Ed. Hunninghake), Upsher-Smith Laboratories, 1-7 (1990).

<sup>†\*\*</sup> "Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults," The Expert Panel, *Arch. Intern. Med.*, 148:36-69 (1988).

Handbook of Nonprescription Drugs, Nutritional Supplements, 9th Edition, American Pharmaceutical Association, 470-471 (1990).

"Clofibrate and Niacin in Coronary Heart Disease," The Coronary Project Research Group, *JAMA*, 231(4):360-381 (1975).

Abumrad, N.A., et al., "Studies on Serum lipids, Insulin, and Glucagon and on Muscle Triglyceride in Rats Adapted to High-fat and High-carbohydrate Diets," *J. Lipid Res.*, 19:423-432 (1978).

Alderman, J.D., et al., "Major Favorable Changes in cholesterol and HDL in Coronary Patients Using a Modified Niacin Regimen," *Clin. Res.*, Abstract 1883, III-471 (1985).

Alderman, J.D., et al., "Effect of a Modified, Well-Tolerated Niacin Regimen on Serum Total Cholesterol, High Density Lipoprotein Cholesterol and the Cholesterol to High Density Lipoprotein Ratio," *Am. J. Cardiol.*, 64(12):725-729 (1989).

Altschul, R., et al., "Influence of Oxygen Inhalation on Cholesterol Metabolism," Letters to the Editors, *Arch. Biochem. Biophys.*, 51:308-309 (1954).

Altschul, R., et al., "Influence of Nicotinic Acid on Serum Cholesterol in Man," Letters to the Editors, *Arch. Biochem. Biophys.* 54:558-559 (1955).

Altschul, R., et al., "Niacin In Vascular Disorders And Hyperlipemia," Charles C. Thomas Publ., Springfield, IL., 42-47; 116-133 (1964).

Andreotti, F., et al., "Major Circadian Fluctuations in Fibrinolytic Factors and Possible Relevance to Time of Onset of Myocardial Infarction, Sudden Cardiac Death and Stroke," *Am. J. Cardiol.*, 62:635-637 (1988).

Angleton, P., et al., "Diurnal Variation of Tissue-Type Plasminogen Activator and Its Rapid Inhibitor (PAI-1)," *Circulation*, 79(1):101-106 (1989).

Barter, P.J., et al., "Diurnal Fluctuations in Triglyceride, Free Fatty Acids, and Insulin During Sucrose Consumption and Insulin Infusion in Man," *J. Clin. Invest.*, 50:583-591 (1971).

Berge, K.G., et al., "Hypercholesteremia and Nicotinic Acid: A Long-Term Study," *Am. J. Med.*, 31:24-35 (1961).

Blankenhorn, D.H., et al., "Beneficial Effects of Combined Colestipol-Niacin Therapy on Coronary Atherosclerosis and Coronary Venous Bypass Grafts," *JAMA*, 257(23):3233-3240 (1987).

Blum, C.B., et al., "Current Therapy for Hypercholesterolemia," *JAMA*, 261(24):3582-3587 (1989).

Brown, G., et al., "Regression of Coronary Artery Disease as a Result of Intensive Lipid-Lowering Therapy in Men with High Levels of Apolipoprotein B," *N. Engl. J. Med.*, 323(19):1289-1298 (1990).

Buri, P., et al., "Formulation des comprimés à libération prolongée II. Matrices hydrophiles," ("Formulation of sustained-release tablets. II. Hydrophilic matrices") *Pharm. ACTA Helv.*, 33(7-8):189-197 (1980) (with English translation of the abstract).

Canner, P.L., et al., "Fifteen Year Mortality in Coronary Drug Project Patients: Long-Term Benefit With Niacin," *J. Am. Coll. Cardiol.*, 8(6):1245-1255 (1986).

Carlson, L.A., "Inhibition of the Mobilization of Free Fatty Acid from Adipose Tissue," *Ann. N.Y. Acad. Sci.*, III(471):119-142.

Carlson, L.A., et al., "The Effect of Nicotinic Acid on the Plasma Free Fatty Acids: Demonstration of a Metabolic Type of Symphathicolysis," *Acta Med. Scand.*, 172:641-645 (1962).

Carlson, L.A., "Studies on the Effect of Nicotinic Acid on Catecholamine Stimulated Lipolysis in Adipose Tissue in Vitro," *Acta Med. Scand.*, 173:719-722 (1963).

Carlson, L.A., et al., "Acute Effects of Nicotinic Acid in the Rat. I. Plasma and Liver Lipids and Blood Glucose," *Acta Med. Scand.*, 179:453-461 (1966).

Carlson, L.A., "Determination of Free Nicotinic Acid in Blood Plasma," *Clin. Chim. Acta*, 13:349-351 (1966).

Carlson, L.A., et al., "Consequences of Inhibition of Normal and Excessive Lipid Mobilization. Studies with Nicotonic Acid," *Prog. Biochem. Pharmacol.*, 3:151-166 (1967).

Carlson, L.A., et al., "Effect of a Single Dose of Nicotinic Acid on Plasma Lipids in Patients with Hyperlipoproteinemia," *Acta Med. Scand.*, 183:457-465 (1968).

Carlson, L.A., et al., "Plasma Lipids and Urinary Excretion of Catecholamines in Man during Experimentally Induced Emotional Stress, and Their Modification by Nicotinic Acid," *J. Clin. Invest.*, 47:1795-1805 (1968).

Carlson, L.A., et al., "Pronounced Lowering of Serum Levels of Lipoprotein Lp(a) in Hyperlipidaemic Subjects Treated with Nicotinic Acid," *J. Int. Med.*, 226(5):271-276 (1989).

Cayen, M.N., "Metabolic Disposition of Antihyperlipidemic Agents in Man and Laboratory Animals," *Drug Metab. Rev.*, 11(2):291-323 (1980).

Cayen, M.N., et al., "Effect of AY-25,712 on Fatty Acid Metabolism in Rats," *Atherosclerosis*, 45(3):281-290 (1982).

Chandler, W.L., et al., "Insulin, Cortisol and Catecholamines Do Not Regulate Circadian Variations in Fibrinolytic Activity," *Thrombosis Res.*, 58(1):1-12 (1990).

Chowhan, Z.T., et al., "Hardness Increase Induced by Partial Moisture Loss in Compressed Tablets and Its Effect on *In Vitro* Dissolution," *J. Pharm. Sci.*, 67(10):1385-1389 (1978).

Chowhan, Z.T., "Role of Binders in Moisture-Induced Hardness Increase in Compressed Tablets and Its Effect on *In Vitro* Disintegration and Dissolution," *J. Pharm. Sci.*, 69(1):1-3 (1980).

Chowhan, Z.T., et al., "Compression Properties of Granulations Made with Binders Containing Different Moisture Contents," *J. Pharm. Sci.*, 70(10):1134-1139 (1981).

Christensen, N.A., et al., "Nicotinic Acid Treatment of Hypercholesteremia, Comparison of Plain and Sustained-Action

Preparations and Report of Two Cases of Jaundice" *JAMA*, 177(8):76-80 (1961).

Cooper, K.H., "The Wisdom and Risk of Drug and Vitamin Therapy," *Dr. Kenneth H. Cooper's Preventive Medicine Program, Controlling Cholesterol*, 244-252, Bantam Books, (1988).

Criscuoli, M., et al., "Glunicate (LG 13979) Protects the Arterial Wall from Cholesterol-Induced Atherosclerotic Changes in the Rabbit Without Affecting Plasma Lipids," *Atherosclerosis*, 53(1):59-68 (1984).

Dalton, T.A., et al., "Hepatotoxicity Associated with Sustained-Release Niacin," *Am. J. Med.*, 93(1):102-104 (1992).

Davis, S.S., et al., *Modern Concepts in Nitrate Delivery Systems*, 30-37, (Eds. A.A.J. Goldberg, D.G. Parsons), 1983 Royal Soc. of Med. Int'l. Cong. & Symp. Series No. 54, published jointly by Academic Press Inc. (London) Ltd. and Royal Society of Medicine.

Dow, "Formulating for Controlled Release with METHOCEL Premium Cellulose Ethers," Dow Chemical Company publications, 1-33 (1995).

Dow, "METHOCEL as a Binding Agent for Tablet Production by Wet Granulation," Dow Chemical Company publication, 1-15 (1985).

Dow, "Viscosity: Molecular Weight-Viscosity Relationship," Handbook on METHOCEL\* Cellulose Ether Products, Dow Chemical Company publication (1974).

Dow, "Technical Information: Methods of Formulating Controlled Release Products Outside the Forest Lab Patent US 4,389,393 Claims."

Dow, "Formulating Sustained Release Pharmaceutical Products with METHOCEL," Dow Chemical Company publication.

Dow, product designation changes for METHOCEL cellulose ethers, Dow Chemical Co. publication (1985) (CZ).

Dow, product designation changes for METHOCEL cellulose ethers, Dow Chemical Co. publication (DG) (1960).

Ekström-Jodal, B., et al., "Influence of Nicotinic Acid and Pentaerythritoltetranicotinate (Perycit<sup>®</sup>, Bofors) on the Cardiac Output in Man," *Pharmacologia Clinica*, 2:86-89 (1970).

Etchason, J.A., et al., "Niacin-Induced Hepatitis: A Potential Side Effect with Low-Dose Time-Release Niacin," *Mayo Clin. Proc.*, 66:23-28 (1991).

Figge, H.L., et al., "Comparison of Excretion of Nicotinuric Acid After Ingestion of Two Controlled Release Nicotinic Acid Preparations in Man," *J. Clin. Pharmacol.*, 28:1135-1140 (1988).

Figge, H.L., et al., "Nicotinic Acid: A Review of Its Clinical Use in the Treatment of Lipid Disorders," *Pharmacotherapy*, 8(5):287-294 (1988).

Fleischman, A.I., et al., Low Dose Sustained Release Nicotinic Acid As An Effective Hypo Lipidemic Agent In Man," *Fed. Proc.*, 34(1):248 (1975).

<sup>†</sup>\*\* Gray, D.R., et al. "Efficacy and Safety of Controlled-release Niacin in Dyslipoproteinemic Veterans," *Ann. Intern. Med.* 121: 252-258 (1994).

Gudsoorkar, V.R., et al., "Influence of Binders on Some Physical Parameters of Lactose and Sulfadimidine Tablets," *Indian Drugs & Pharmaceuticals Industry*, 3-4 (Jul.-Aug. 1980).

Hamsten, A., et al., "Increased Plasma Levels of a Rapid Inhibitor of Tissue Plasminogen Activator in Young Survivors of Myocardial Infarction," *N. Engl. J. Med.*, 313(25):1557-1563 (1985).

Henkin, Y., et al., "Rechallenge With Crystalline Niacin After Drug-Induced Hepatitis From Sustained-Release Niacin," *JAMA*, 264(2):241-243 (1990).

Henkin, Y., et al., "Niacin Revisited: Clinical Observations on an Important but Underutilized Drug," *Am. J. Med.*, 91:239-246 (1991).

Hodis, H.N., "Acute Hepatic Failure Associated With the Use of Low-Dose Sustained-Release Niacin," Letter to the Editors, *JAMA* 264(2):181 (1990).

Huber, H.E., et al., "Utilization of Hydrophilic Gums for the Control of Drug Release from Tablet Formulations I. Disintegration and Dissolution Behavior," *J. Pharm. Sci.*, 55(9):974-976 (1966).

Ibrahim, S.A., et al., "Release Characteristics of Oxyphenbutazone from Different Suppository Bases," *Pharmazie*, 35(8):567 (1980).

Jacobson, T.A., et al., "Combination Therapy with Fluvastatin and Niacin in Hypercholesterolemia: A Preliminary Report on Safety," *Am. J. Cardiol.*, 73:25D-29D (1994).

Kane, J.P., et al., "Normalization of Low-Density-Lipoprotein Levels in Heterozygous Familial Hypercholesterolemia with a Combined Drug Regimen," *N. Engl. J. Med.*, 304(5):251-258 (1981).

Kassem, A.A., et al., "Enhancement of Release Rate of Spironolactone from Its Tablets by the Formation of Solid Dispersions with Water-Soluble Polymers," *Jami et Al-Qahira, Faculty of Pharmacy, Cairo University, Bulletin, Cairo*, 19(1):275-306 (1980).

Keenan, J.M., et al., "Niacin Revisited: A Randomized, Controlled Trial of Wax-Matrix Sustained-Release Niacin in Hypercholesterolemia," *JAMA Spec. J. Abst.*, 266(16):2209 (1991).

Keenan, J.M., et al., "Niacin Revisited A Randomized, Controlled Trial of Wax-Matrix Sustained-Release Niacin in Hypercholesterolemia," *Arch. Intern. Med.*, 151:1424-1432 (1991).

Keenan, J.M., et al., "Treatment of Hypercholesterolemia: Comparison of Younger versus Older Patients Using Wax-Matrix



Sustained-Release Niacin," *J. Am. Geriatr. Soc.*, 40:12-18 (1992).

King, R.E., "Tablets, Capsules, and Pills," *Remington's Pharm. Sci.*, 1576-1587 (1975).

Kirschstein, W., et al., "Impaired Fibrinolytic Capacity and Tissue Plasminogen Activator Release in Patients with Restenosis after Percutaneous Transluminal Coronary Angioplasty (PTCA)," *Thromb. Haemost.*, 62(2):772-775 (1989).

Knopp, R.H., et al., "Contrasting Effects of Unmodified and Time-Release Forms of Niacin on Lipoproteins in Hyperlipidemic Subjects: Clues to Mechanism of Action of Niacin," *Metabolism*, 34(7):642-650 (1985).

Korsmeyer, R.W., et al., "Mechanisms of Potassium Chloride Release from Compressed, Hydrophilic, Polymeric Matrices: Effect of Entrapped Air," *J. Pharm. Sci.*, 72(10):1189-1191 (1983).

Kowalski, R.E., *The 8-Week Cholesterol Cure*, Harper & Row, Publishers, 95-115 (1989).

Kruse, W., et al., "Nocturnal Inhibition of Lipolysis in Man by Nicotinic Acid and Derivatives," *Eur. J. Clin. Pharmacol.*, 16:11-15 (1979).

Krycer, I., et al., "An Evaluation of Tablet Binding Agents Part I. Solution Binders," *Powder Technol.*, 34:39-51 (1983).

Laguna, O., et al., "Enrobage. III. Influence de quelques produits filmogènes et plastifiants sur la dissolution de comprimés à base de chlorure de sodium," ("Coatings. III. Influence of various filmogenic products and plasticizers on the dissolution of tablets with a sodium chloride base") *Ann. Pharm. Fr.*, 33(5):235-242 (1975). This document relates to the dissolution properties of sodium chloride-based tablets coated with filmogenic products and plasticizers.

Lapidus, H., et al., "Some Factors Affecting The Release of a Water-Soluble Drug from a Compressed Hydrophilic Matrix," *J. Pharm. Sci.*, 55(8):840-843 (1966).

- Lapidus, H., "Drug Release from Compressed Hydrophilic Matrices," *University Microfilms International*, Thesis, Rutgers University, 1-117 (1967).
- Lapidus, H., *Chemistry, Abstract*, (order No. 67-14,728) 2363-B2364-B (1967).
- Lapidus, H., et al., "Drug Release From Compressed Hydrophilic Matrices," *J. Pharm. Sci.*, 57(8):1292-1301 (1968).
- Leiner, P., Chain Drug Review Publication, 12 (Jun. 6, 1988).
- Luria, M.H., "Effect of Low-Dose Niacin on High-Density Lipoprotein Cholesterol and Total Cholesterol/High-Density Lipoprotein Cholesterol Ratio," *Arch. Intern. Med.*, 148:2493-2495 (1988).
- Mahl, M., et al., "A Long Term Study of the Effect of Nicotinic Acid Medication on Hypercholesteremia," *Am. J. Med. Sci.*, 64:673-677 (1963).
- Malkowska, S., et al., "Effect of Re-Compression on the Properties of Tablets Prepared by Moist Granulation," *Drug Dev. Indust. Pharmacy*, Marcel Dekker, Inc., 9(3):349-361 (1983).
- Manninen, M., et al., "Lipid Alterations and Decline in the Incidence of Coronary Heart Disease in the Helsinki Heart Study," *JAMA*, 260(5):641-651 (1988).
- Merck & Co. Inc., The Merck Index, Tenth Ed., 809, 520, 351, 466 (1983).
- Miettinen, T.A., "Diurnal Variation of LDL and HDL Cholesterol," *Ann. Clin. Res.*, 12:295-298 (1980).
- Miettinen, T.A., "Cholesterol Precursors and Their Diurnal Rhythm in Lipoproteins of Patients with Jejuno-Ileal Bypass and Ileal Dysfunction," *Metabolism*, 34(5):425-430 (May 1985).
- Miettinen, T.A. "Diurnal Variation of Cholesterol Precursors Squalene and Methyl Sterols in Human Plasma Lipoproteins," *J. Lipid Res.*, 23:466-473 (1982).

Miettinen, T.A., "Detection of Changes in Human Cholesterol Metabolism," *Ann. Clin. Res.*, 2:300-320 (1970).

Miller, O.N., et al., "Investigation of the Mechanism of Action of Nicotinic Acid on Serum Lipid Levels in Man," *Am. J. Clin. Nutr.*, 8:480-490 (1960).

Muller, J.E. et al., "Circadian Variation in the Frequency of Sudden Cardiac Death," *Circulation*, 75(1):131-138 (1987).

Nagy, G. et al., "Untersuchungen über die Textur und die Eigenschaften von Acetylsalicylsäure-Tabletten 1. Mitteilung: Ein Fluß der Herstellung-sweise auf die Eigenschaften der Tabletten," ("The texture and properties of acetylsalicylic acid tablets. 1. The effect of manufacturing methods on the properties of tablets") *Pharmazie*, 33(1):747-749 (1978). This document relates to the effect of manufacturing methods on the properties and textures of acetylsalicylic acid tablets.

Neuvonen, P.J., et al., "The Bioavailability of Sustained Release Nicotinic Acid Formulations," *Br. J. Clin. Pharmacol.*, 32:473-476 (1991).

Pinter, E.J. et al., "Biphasic Nature of Blood Glucose and Free Fatty Acid Changes Following Intravenous Nicotinic Acid in Man," *J. Clin. Endocrinol. Metab.*, 27:440-443 (1967).

Pintye-Hodi, K., et al., "Untersuchungen über die Textur und die Eigenschaften von Acetylsalicylsäure-Tabletten 2. Mitteilung: Untersuchung der Textur durch Feuchtgranulierung bereiteter Tabletten," *Pharmazie*, 35(3):168-170 (1980) (with English translation of Abstract attached).

Rader, J.I., et al., "Hepatic Toxicity of Unmodified and Time-Release Preparations of Niacin," *Am. J. Med.*, 92:77-81 (1992).

Remington's Pharmaceutical Sciences, 15<sup>th</sup> Ed., 1242-1251, Mack Publishing Co., Easton, PA (1975).

\*\* Remington's Pharmaceutical Sciences, 18<sup>th</sup> Ed., 1636-1637, Mack Publishing Co., Easton, PA (1990).

† Remington's Pharmaceutical Sciences, 1304-1323; 1676-1686, Mack Publishing Co. Easton, PA (1990).

Renzetti, A.R., et al., "Further Assessment of Glunilate Hypolipidaemic Activity in the Rat," *J. Pharm. Pharmacol.*, 37(12):906-909 (1985).

Ross, R. "The Pathogenesis of Atherosclerosis-An Update," *N. Engl. J. Med.*, 314:488-500 (1986).

Rowland, M., et al., *Clinical Pharmacokinetics: Concepts and Applications*, Les & Feiger, 111 (1980).

Salomon, J-L., et al., "Importance de la technologie et de la formulation pour le mécanisme de libération du chlorure de potassium contenu dans des matrices hydrophiles 1. Influence de la viscosité et du pourcentage de gélifiant," ("Importance of technology and formulation for the mechanism of continuous liberation of potassium chloride from hydrophilic matrices. 1. Effect of viscosity and percentage of excipient") *Pharm. ACTA Helv.*, 54(3):82-85 (1979) (with English translation of Abstract).

Salomon, J-L., et al., "Sustained Release of a Water-Soluble Drug from Hydrophilic Compressed Dosage Forms," *Pharm. Ind.*, 41(8):799-802 (1979).

Schlierf, G., et al., "Diurnal Patterns of Triglycerides, Free Fatty Acids, Blood Sugar, and Insulin During Carbohydrate-Induction in Man and Their Modification by Nocturnal Suppression of Lipolysis," *J. Clin. Invest.*, 52:732-740 (1973).

Schlierf, G., et al., "Inhibition of Carbohydrate-Induced Hypertriglyceridemia by Nicotinic Acid," *Artery*, 3(2):174-179 (1977).

Schlierf, G., et al., "Diurnal Patterns of Plasma Triglycerides and Free Fatty Acids in Normal Subjects and in Patients with Endogenous (Type IV) Hyperlipoproteinemia," *Nutr. Metabol.*, 13:80-91 (1971).

Schlierf, G., et al., "Modification of 'Carbohydrate-Induced' Triglyceridemia by Nocturnal Suppression of Lipolysis -

Comparison of Nicotinic Acid and Glucose," *Pharmacological Control of Lipid Metabolism, Proceedings of the Fourth International Symposium on Drugs Affecting Lipid Metabolism, Philadelphia, PA*, 26:319-320 (1971).

Schulman, K.A., et al., "Reducing High Blood Cholesterol Level With Drugs - Cost-effectiveness of Pharmacologic Management," *JAMA*, 264(23):3025-3033 (1990).

Shepherd, J., et al., "Effects of Nicotinic Acid Therapy on Plasma High Density Lipoprotein Subfraction Distribution and Composition and on Apolipoprotein A Metabolism," *J. Clin. Invest.*, 63:858-867 (1979).

Sokoloski, T.T., "Solutions and Phase Equilibria," *Remington's Pharmaceutical Sciences*, 17<sup>th</sup> Ed., 207-208, Mack Publishing Co., Easton, PA (1985).

Sprengers, E.D., et al., "Plasminogen Activator Inhibitors" *Blood*, 69(2):381-387 (1987).

Squires, R.W., et al., "Low-Dose, Time-Release Nicotinic Acid: Effects in Selected Patients With Low Concentrations of High-Density Lipoprotein Cholesterol," *Mayo Clin. Proc.*, 67(9):855-860 (1992).

Subissi, A., et al., "Acute Effects on Plasma Lipids in the Rat of a New Long-Acting Nicotinic Acid Derivative: LG 13979," *J. Pharm. Pharmacol.*, 35:571-575 (1983).

Svedmyr, N., et al., "The Relationship Between the Plasma Concentration of Free Nicotinic Acid and Some of Its Pharmacologic Effects in Man," *Clin. Pharm. Ther.*, 4(10):559-570 (1969).

Urberg, M., et al., "Evidence for Synergism Between Chromium and Nicotinic Acid in the Control of Glucose Tolerance in Elderly Humans," *Metabolism*, 36(9):896-899 (1987).

Urburg, M., et al., "Hypocholesterolemic Effects of Nicotinic Acid and Chromium Supplementation," *J. Family Practice*, 27(6):603-606 (1988).

Wahlberg, G., et al., "Effects of Nicotinic Acid on Concentrations of Serum Apolipoproteins B, C-1, C-II, C-III and E in Hyperlipidemic Patients," *Acta Med. Scand.*, 224:319-327 (1988).

Wiman, B., et al., "The Role of the Fibrinolytic System in Deep Vein Thrombosis," *J. Lab. Clin. Med.*, 105(2):265-270 (1985).

The above-identified application is a continuation-in-part of United States application 08/814,974 ("the '974 application"), filed March 6, 1997, now United States patent 6,129,930 ("the '930 patent"); which is a continuation-in-part of United States application 08/368,378, filed January 14, 1995, now United States patent 6,080,428 ("the '428 patent"); which is a continuation-in-part of United States application 08/124,392, filed September 20, 1993, now abandoned.

Applicant makes of record the documents listed below, from litigations involving the '930 patent, the '428 patent and United States patent 6,406,715, which claims priority from the '974 application:

\*\* Complaint, filed by Kos Pharmaceuticals, Inc. against Barr Laboratories on March 4, 2002, in Civil Action No. 02 CV 1683.

\*\* First Amended Complaint, filed by Kos Pharmaceuticals, Inc. on March 11, 2002, in Civil Action No. 02 CV 1683.

\*\* Answer To First Amended Complaint, filed by Barr Laboratories on March 25, 2002, in Civil Action No. 02 CV 1683.

\*\* Reply To Counterclaims, filed by Kos Pharmaceuticals, Inc. on April 15, 2002, in Civil Action No. 02 CV 1683.

\*\* Amended Answer To First Amended Complaint, filed by Barr Laboratories on August 19, 2002, in Civil Action No. 02 CV 1683.

\*\* Complaint, filed by Kos Pharmaceuticals, Inc. on August 13, 2002, in Civil Action No. 02 CV 6409.

\*\* Answer To Complaint, filed by Barr Laboratories on September 3, 2002, in Civil Action No. 02 CV 6409.

\*\* Complaint, filed by Kos Pharmaceuticals, Inc. on November 12, 2002, in Civil Action No. 02 CV 8995.

\*\* Answer To Complaint, filed by Barr Laboratories on December 3, 2002, in Civil Action No. 02 CV 8995.

\*\* Reply To Counterclaims And Counterclaims For Declaratory Judgment, filed by Kos Pharmaceuticals, Inc. on March 4, 2003, in Civil Action No. 02 CV 8995.

The majority of the art cited herein has been previously considered by the Examiner in the applications from which this application claims priority. Art that is being cited to the Examiner for the first time is indicated by asterisks on this Statement and by a flag on the document itself.

Applicant requests that the above-cited documents be: (1) fully considered by the Examiner during the course of the examination of this application; and (2) printed on any patent that may issue from this application.

Applicant also requests that a copy of Form PTO-1449, as considered and initialled by the Examiner, be returned to the undersigned with the next Communication.

Respectfully submitted,

5/2/03

Date



Karen J. Messick (Reg. No. 46,256)

Attorney for Applicant

c/o Kos Pharmaceuticals, Inc.

1001 Brickell Bay Drive

25th Floor

Miami, Florida 33131

Tel.: (305) 523-3643



<b>FORM PTO-1449</b> <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	Re. 29,652	05/30/1978	Fields et al.			
	Re. 32,581	01/19/1998	Scherm et al.			
	2,510,164	06/06/1950	Woodward et al.			
	2,540,979	02/06/1951	Clymer et al.			
	2,749,274	06/05/1956	Buckwalter			
	2,798,837	07/09/1957	Sahyun			
	2,798,838	07/09/1957	Robinson			
	2,805,977	09/10/1957	Robinson et al.			
	2,851,453	09/09/1958	Kennon et al.			
	2,857,313	10/21/1958	Cooper et al.			
	2,887,436	05/19/1959	Klioze et al.			
	2,957,804	10/25/1960	Schuyler			
	3,062,720	11/06/1962	Costello			
	3,065,143	11/20/1962	Christenson et al.			
	3,108,046	10/22/1963	Harbit			
	3,116,204	12/31/1963	Siegel et al.			
	3,134,719	05/26/1964	Sheth et al.			
	3,143,469	08/04/1964	Debay et al.			
	3,147,187	09/01/1964	Playfair			
	3,193,461	07/06/1965	Eisen			
	3,210,413	10/05/1965	Blank et al.			
	3,272,832	09/13/1966	Nakano et al.			
	3,336,200	08/15/1967	Krause et al.			
	3,424,842	01/28/1969	Nürnberg			
	3,495,011	02/10/1970	Fossel			

RECEIVED  
 MAR 05 2003  
 TECH CENTER 1600/2900

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b> <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	3,590,117	06/29/1971	Christenson et al.			
	3,626,071	12/21/1971	Kariya et al.			
	3,629,393	12/21/1971	Nakamota et al.			
	3,629,453	12/21/1971	Waring			
	3,634,584	01/11/1972	Poole			
	3,639,636	02/01/1972	Barnhart			
	3,709,991	01/09/1973	Miller			
	3,721,735	03/20/1973	Thiffault			
	3,773,920	11/20/1973	Nakamoto et al.			
	3,795,691	03/05/1974	Douglas et al.			
	3,806,601	04/23/1974	Mikite et al.			
	3,849,554	11/19/1974	Winitz			
	3,859,437	01/07/1975	Weigand			
	3,862,332	01/21/1975	Barnhart et al.			
	3,864,416	02/25/1975	Albright et al.			
	3,870,790	03/11/1975	Lowey et al.			
	3,923,972	12/02/1975	Fields et al.			
	3,924,001	12/02/1975	Albright et al.			
	3,930,017	12/30/1975	Kummer et al.			
	3,951,821	04/20/1976	Davidson			
	3,957,976	05/18/1976	Sugimoto			
	3,959,492	05/25/1976	Coulston et al.			
	3,965,255	06/22/1976	Bloch et al.			
	3,977,404	08/31/1976	Theeuwes			
	3,987,160	10/19/1976	Broughton et al.			

RECEIVED  
 OCT 10 2003  
 TECH CENTER 1600/12000

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b> <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	3,992,536	11/16/1976	Kleemann			
	4,002,641	01/11/1977	Möller et al.			
	4,008,719	02/22/1977	Theeuwes et al.			
	4,011,339	03/08/1977	Galantay et al.			
	4,014,334	03/29/1977	Theeuwes et al.			
	4,014,987	03/29/1977	Heller et al.			
	4,034,087	07/05/1977	Voorhees			
	4,034,758	07/12/1977	Theeuwes			
	4,058,122	11/15/1977	Theeuwes et al.			
	4,067,876	01/10/1978	Ferutti et al.			
	4,077,407	03/07/1978	Theeuwes et al.			
	4,102,806	07/25/1978	Kondo et al.			
	4,115,550	09/19/1978	Fields et al.			
	4,116,241	09/26/1978	Theeuwes et al.			
	4,117,111	09/26/1978	Fields et al.			
	4,126,672	11/21/1978	Sheth et al.			
	4,140,755	02/20/1979	Sheth et al.			
	4,160,020	07/03/1979	Ayer et al.			
	4,160,452	07/10/1979	Theeuwes			
	4,166,902	09/04/1979	Ferruti			
	4,167,558	09/11/1979	Sheth et al.			
	4,169,944	10/02/1979	Scallen et al.			
	4,178,387	12/11/1979	Diamond et al.			
	4,180,064	12/25/1979	Heller et al.			
	4,182,902	01/08/1980	Thiele et al.			

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b> <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,203,439	05/20/1980	Theeuwes			
	4,205,085	05/27/1980	Shepherd			
	4,211,783	07/08/1980	Shepherd			
	4,226,849	10/07/1980	Schor			
	4,230,878	10/28/1980	Shepherd			
	4,237,118	12/02/1980	Howard			
	4,248,857	02/03/1981	DeNeale et al.			
	4,251,519	02/17/1981	Robbins et al.			
	4,255,449	03/10/1981	Cavazza			
	4,256,108	03/17/1981	Theeuwes			
	4,259,314	03/31/1981	Lowey			
	4,261,970	04/14/1981	Ogawa et al.			
	4,268,524	05/19/1981	Cavazza			
	4,272,548	06/09/1981	Gatzen et al.			
	4,279,898	07/21/1981	Engel et al.			
	4,282,233	08/04/1981	Vilani			
	4,283,382	08/11/1981	Frank et al.			
	4,285,951	08/25/1981	Hoefle			
	4,291,030	09/22/1981	Mulinos			
	4,305,959	12/15/1981	Shepherd			
	4,308,251	12/29/1981	Dunn et al.			
	4,309,404	01/05/1982	DeNeale et al.			
	4,310,545	01/12/1982	Shepherd			
	4,318,914	03/09/1982	Shepherd			
	4,326,525	04/27/1982	Swanson et al.			

RECEIVED  
MAY 05 2008  
TECH CENTER 1600/2900

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b>  <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

### U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,348,399	09/07/1982	Shepherd			
	4,353,887	10/12/1982	Hess et al.			
	4,357,469	11/02/1982	Schor			
	4,361,546	11/30/1982	Stricker et al.			
	4,362,711	12/07/1982	Cerami			
	4,367,217	01/04/1983	Gruber et al.			
	4,369,172	01/18/1983	Schor et al.			
	4,375,468	03/01/1983	Dunn			
	4,382,143	05/03/1983	Shepherd			
	4,389,393	06/21/1983	Schor et al.			
	4,428,951	01/31/1984	Hata et al.			
	4,432,966	02/21/1984	Zeitoun et al.			
	4,440,940	04/03/1984	Shepherd			
	4,452,775	06/05/1984	Kent			
	4,454,108	06/12/1984	Iida et al.			
	4,455,298	06/19/1984	McFarlane et al.			
	4,457,907	07/03/1984	Porter et al.			
	4,461,759	07/24/1984	Dunn			
	4,465,660	08/14/1984	David et al.			
	4,472,436	09/18/1984	Hooper			
	4,478,819	10/23/1984	Hercelin et al.			
	4,485,105	11/27/1984	Shepherd			
	4,505,890	03/19/1985	Jain et al.			
	4,522,804	06/11/1985	Dunn			
	4,525,345	06/25/1985	Dunn et al.			

RECEIVED  
 MAY 05 2003  
 TECH CENTER 16002900

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b>  <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,539,198	09/03/1985	Powell et al.			
	4,540,566	09/10/1985	Davis et al.			
	4,547,359	10/15/1985	Zierenberg et al.			
	4,556,678	12/03/1985	Hsiao et al.			
	4,568,547	02/04/1986	Herschler			
	4,571,333	02/18/1986	Hsiao			
	4,576,604	03/18/1986	Guittard et al.			
	4,603,142	07/29/1986	Burger et al.			
	4,605,666	08/12/1986	Schmidt et al.			
	4,610,870	09/09/1986	Jain et al.			
	4,624,950	11/25/1986	Sasaki et al.			
	4,657,757	04/14/1987	Hanna et al.			
	4,673,405	06/16/1987	Guittard et al.			
	4,678,516	07/07/1987	Alderman et al.			
	4,680,323	07/14/1987	Lowey			
	4,684,516	08/04/1987	Bhutani			
	4,690,824	09/01/1987	Powell et al.			
	4,692,337	09/08/1987	Ukigaya et al.			
	4,695,467	09/22/1987	Uemura et al.			
	4,695,591	09/22/1987	Hanna et al.			
	4,695,910	09/22/1987	Maruyama et al.			
	4,696,762	09/29/1987	Sander et al.			
	4,704,285	11/03/1987	Alderman			
	4,708,834	11/24/1987	Cohen et al.			
	4,710,519	12/01/1987	Finnan et al.			

RECEIVED  
 MAY 10 5 2003  
 TECH CENTER 1600/2910

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b> <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

### U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,713,245	12/15/1987	Ando et al.			
	4,729,895	03/08/1988	Makino et al.			
	4,734,285	03/29/1988	Alderman			
	4,744,907	05/17/1988	Klimchak et al.			
	4,747,881	05/31/1988	Shaw et al.			
	4,749,575	06/07/1988	Rotman			
	4,752,479	06/21/1988	Briggs et al.			
	4,753,801	06/28/1988	Oren et al.			
	4,755,544	07/05/1988	Makino et al.			
	4,756,911	07/12/1988	Drost et al.			
	4,758,581	07/19/1988	Scherm et al.			
	4,759,923	07/26/1988	Buntin et al.			
	4,764,374	08/16/1988	Grimberg			
	4,775,483	10/04/1988	Mookerjea et al.			
	4,775,535	10/04/1988	Lowey			
	4,777,042	10/11/1988	Toda et al.			
	4,784,858	11/15/1988	Ventouras			
	4,789,549	12/06/1988	Khan et al.			
	4,792,452	12/20/1988	Howard et al.			
	4,792,554	12/20/1988	Elben et al.			
	4,794,115	12/27/1988	Takahasi et al.			
	4,795,327	01/03/1989	Gaylord et al.			
	4,795,642	01/03/1989	Cohen et al.			
	4,795,644	01/03/1989	Zentner			
	4,803,079	02/07/1989	Hsiao et al.			

RECEIVED  
 MAY 05 2003  
 TECH CENTER 1600/2900

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b>  <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,803,081	02/07/1989	Falk et al.			
	4,812,316	03/14/1989	Rossi et al.			
	4,814,183	03/21/1989	Zentner			
	4,814,354	03/21/1989	Ghere-Sellassie et al.			
	4,824,672	04/25/1989	Day et al.			
	4,824,677	04/25/1989	Shah et al.			
	4,828,836	05/09/1989	Elger et al.			
	4,830,859	05/16/1989	Finnan			
	4,834,965	05/30/1989	Martani et al.			
	4,834,985	05/30/1989	Elger et al.			
	4,837,032	06/06/1989	Ortega			
	4,839,177	06/13/1989	Colombo et al.			
	4,842,863	06/27/1989	Nishimura et al.			
	4,844,907	07/04/1989	Elger et al.			
	4,849,229	07/18/1989	Gaylord et al.			
	4,851,232	07/25/1989	Urquhart et al.			
	4,851,233	07/25/1989	Khan et al.			
	4,855,143	08/08/1989	Lowey			
	4,857,336	08/15/1989	Khanna et al.			
	4,866,058	09/12/1989	Izydore et al.			
	4,871,548	10/03/1989	Edgren et al.			
	4,882,167	11/21/1989	Jang			
	4,886,669	12/12/1989	Ventouras			
	4,888,178	12/19/1989	Rotini et al.			
	4,892,741	01/09/1990	Ohm et al.			

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.



<b>FORM PTO-1449</b> <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

### U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,911,917	03/27/1990	Kuhrts			
	4,915,952	04/10/1990	Ayer et al.			
	4,920,115	04/24/1990	Nestler et al.			
	4,920,123	04/24/1990	Beyer, Jr.			
	4,925,905	05/15/1990	Boeckh et al.			
	4,935,246	06/19/1990	Ahrens			
	4,940,588	07/10/1990	Sparks et al.			
	4,942,040	07/17/1990	Ragnarsson et al.			
	4,946,870	08/07/1990	Partain, III et al.			
	4,946,963	08/07/1990	Izydore et al.			
	4,950,689	08/21/1990	Yang et al.			
	4,952,402	08/28/1990	Sparks et al.			
	4,959,478	09/25/1990	Möller et al.			
	4,963,367	10/16/1990	Ecanow			
	4,965,252	10/23/1990	Kuhrts			
	4,966,768	10/30/1990	Michelucci et al.			
	4,968,508	11/06/1990	Oren et al.			
	4,970,081	11/13/1990	Frisbee			
	4,973,468	11/27/1990	Chiang et al.			
	4,973,469	11/27/1990	Mulligan et al.			
	4,983,398	01/08/1991	Gaylord et al.			
	4,990,535	02/05/1991	Cho et al.			
	4,992,278	02/12/1991	Khanna			
	4,994,267	02/19/1991	Sablotsky			
	4,994,276	02/19/1991	Baichwal et al.			

RECEIVED  
 MAY 05 2003  
 TECH CENTER 16001026000

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b> <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

### U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,996,058	02/26/1991	Sinnreich			
	4,997,658	03/05/1991	Alberts et al.			
	4,999,380	03/12/1991	Berger et al.			
	5,002,774	03/26/1991	Agrawala et al.			
	5,009,895	04/23/1991	Lui			
	5,010,105	04/23/1991	Lee			
	5,011,947	04/30/1991	Catt et al.			
	5,015,479	05/14/1991	Mulligan et al.			
	5,023,245	06/11/1991	Kuhrts			
	5,025,012	06/18/1991	Miura et al.			
	5,030,653	07/09/1991	Trivedi			
	5,032,406	07/16/1991	Dansereau et al.			
	5,034,528	07/23/1991	Izydore et al.			
	5,039,341	08/13/1991	Meyer et al.			
	5,047,248	09/10/1991	Calanchi et al.			
	5,049,696	09/17/1991	Lee et al.			
	5,096,714	03/17/1992	Kuhrts			
	5,100,675	03/31/1992	Cho et al.			
	5,110,817	05/05/1992	Beyer, Jr.			
	5,110,940	05/05/1992	Sit et al.			
	5,116,610	05/26/1992	Broadus			
	5,126,145	06/30/1992	Evenstad et al.			
	5,128,142	07/07/1992	Mulligan et al.			
	5,130,333	07/14/1992	Pan et al.			
	5,132,116	07/21/1992	Sournac et al.			

RECEIVED  
 MAY 05 2003  
 TECH CENTER 1600/2900

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b>  <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

### U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,133,974	07/28/1992	Paradissis et al.			
	5,145,678	09/08/1992	Gakic et al.			
	5,167,964	12/01/1992	Muhammad et al.			
	5,169,638	12/08/1992	Dennis et al.			
	5,169,639	12/08/1992	Baichwal et al.			
	5,169,640	12/08/1992	France et al.			
	5,171,570	12/15/1992	Takemori et al.			
	5,178,854	01/12/1993	Asami et al.			
	5,182,298	01/26/1993	Helms et al.			
	5,188,839	02/23/1993	Pearmain			
	5,190,940	03/02/1993	Commons et al.			
	5,190,970	03/02/1993	Pan et al.			
	5,196,440	03/23/1993	Bertolini et al.			
	5,211,958	05/18/1993	Akkerboom et al.			
	5,213,808	05/25/1993	Bar-Shalom et al.			
	5,256,689	10/26/1993	Chiang			
	5,258,401	11/02/1993	Berger et al.			
	5,260,305	11/09/1993	Dennick			
	5,262,165	11/16/1993	Govil et al.			
	5,262,435	11/16/1993	Joshua et al.			
	5,264,226	11/23/1993	Graille et al.			
	5,268,181	12/07/1993	O'Neill et al.			
	5,278,067	01/11/1994	Dawson et al.			

RECEIVED  
 MAY 05 2003  
 TECH CENTER 160012600

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b>  <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,286,736	02/15/1994	Soyka et al.			
	5,314,697	05/24/1994	Kwan et al.			

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	603 690 -	08/16/1960	Canada				
	0 109 320	05/23/1984	EP				
	0 126 453	11/28/1984	EP				
	0 349 235 A2	01/03/1990	EP				
	0 577 504 A1	01/05/1994	EP				
	1 302 362	07/23/1962	France				
	40-2053	02/03/1965	Japan				
	46-18151	05/20/1971	Japan				
	55-049312	09/04/1980	Japan				
	2 141 338	12/19/1984	UK				
	2 154 874	09/18/1985	UK				
	WO84/00104	01/19/1984	PCT				

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b>  <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

EXAMINER INITIAL	
	English language translation of Abstract of Japanese Patent No. JP63310827 A 881219 Derwent DW8905 (1988).
	English language translation of Abstract of Japanese Patent No. JP5221854 A 930831 Derwent DW9339 A61K9/22 (1993).
	Slow Niacin Advertisement, <i>Am. Druggist</i> , 141-142 (1988).
	Regulatory Letter to Upsher-Smith Laboratories (Jun. 6, 1988).
	"Issues in Cholesterol Management: Reappraisal of Niacin," (Ed. Hunninghake), Upsher-Smith Laboratories, 1-7 (1990).
	"Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults," The Expert Panel, <i>Arch. Intern. Med.</i> , 148:36-69 (1988).
	Handbook of Nonprescription Drugs, Nutritional Supplements, 9th Edition, American Pharmaceutical Association, 470-471 (1990).
	"Clofibrate and Niacin in Coronary Heart Disease," The Coronary Project Research Group, <i>JAMA</i> , 231(4):360-381 (1975).
	Abumrad, N.A., et al., "Studies on Serum lipids, Insulin, and Glucagon and on Muscle Triglyceride in Rats Adapted to High-fat and High-carbohydrate Diets," <i>J. Lipid Res.</i> , 19:423-432 (1978).
	Alderman, J.D., et al., "Major Favorable Changes in cholesterol and HDL in Coronary Patients Using a Modified Niacin Regimen," <i>Clin. Res.</i> , Abstract 1883, III-471 (1985).
	Alderman, J.D., et al., "Effect of a Modified, Well-Tolerated Niacin Regimen on Serum Total Cholesterol, High Density Lipoprotein Cholesterol and the Cholesterol to High Density Lipoprotein Ratio," <i>Am. J. Cardiol.</i> , 64(12):725-729 (1989).
	Altschul, R., et al., "Influence of Oxygen Inhalation on Cholesterol Metabolism," Letters to the Editors, <i>Arch. Biochem. Biophys.</i> , 51:308-309 (1954).
	Altschul, R., et al., "Influence of Nicotinic Acid on Serum Cholesterol in Man," Letters to the Editors, <i>Arch. Biochem. Biophys.</i> , 54:558-559 (1955).
	Altschul, R., et al., "Niacin In Vascular Disorders And Hyperlipemia," Charles C. Thomas Publ., Springfield, IL, 42-47; 116-133 (1964).

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b>  <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

EXAMINER INITIAL	
	Andreotti, F., et al., "Major Circadian Fluctuations in Fibrinolytic Factors and Possible Relevance of Time of Onset of Myocardial Infarction, Sudden Cardiac Death and Stroke," <i>Am. J. Cardiol.</i> , 62:635-637 (1988).
	Angleton, P., et al., "Diurnal Variation of Tissue-Type Plasminogen Activator and Its Rapid Inhibitor (PAI-1)," <i>Circulation</i> , 79:101-106 (1989).
	Barter, P.J., et al., "Diurnal Fluctuations in Triglyceride, Free Fatty Acids, and Insulin During Sucrose Consumption and Insulin Infusion in Man," <i>J. Clin. Invest.</i> , 50:583-591 (1971).
	Berge, K.G., et al., "Hypercholesteremia and Nicotinic Acid: A Long-Term Study," <i>Am. J. Med.</i> , 31:24-35 (1961).
	Blankenhorn, D.H., et al., "Beneficial Effects of Combined Colestipol-Niacin Therapy on Coronary Atherosclerosis and Coronary Venous Bypass Grafts," <i>JAMA</i> , 257(23):3233-3240 (1987).
	Blum, C.B., et al., "Current Therapy for Hypercholesterolemia," <i>JAMA</i> , 261(24):3582-3587 (1989).
	Brown, G., et al., "Regression of Coronary Artery Disease as a Result of Intensive Lipid-Lowering Therapy in Men with High Levels of Apolipoprotein B," <i>N. Engl. J. Med.</i> , 323(19):1289-1298 (1990).
	Buri, P., et al., "Formulation des comprimés à libération prolongée II. Matrices hydrophiles," ("Formulation of sustained-release tablets. II. Hydrophilic matrices") <i>Pharm. ACTA Helv.</i> , 33(7-8):189-197 (1980) (with English translation of the abstract).
	Canner, P.L., et al., "Fifteen Year Mortality in Coronary Drug Project Patients: Long-Term Benefit With Niacin," <i>J. Am. Coll. Cardiol.</i> , 8(6):1245-1255 (1986).
	Carlson, L.A., "Inhibition of the Mobilization of Free Fatty Acid from Adipose Tissue," <i>Ann. NY Acad. Sci.</i> , 113(471):119-142.
	Carlson, L.A., et al., "The Effect of Nicotinic Acid on the Plasma Free Fatty Acids: Demonstration of a Metabolic Type of Symphathicolysis," <i>Acta Med. Scand.</i> , 172:641-645 (1962).
	Carlson, L.A., "Studies on the Effect of Nicotinic Acid on Catecholamine Stimulated Lipolysis in Adipose Tissue in Vitro," <i>Acta Med. Scand.</i> , 173:719-722 (1963).
	Carlson, L.A., et al., "Acute Effects of Nicotinic Acid in the Rat. I. Plasma and Liver Lipids and Blood Glucose," <i>Acta Med. Scand.</i> , 179:453-461 (1966).
	Carlson, L.A., "Determination of Free Nicotinic Acid in Blood Plasma," <i>Clin. Chim. Acta</i> , 13:349-351 (1966).

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b>  <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

RECEIVED  
 MAY 05 2003  
 TECH CENTER 1600/2300

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

EXAMINER INITIAL	
	Carlson, L.A., et al., "Consequences of Inhibition of Normal and Excessive Lipid Mobilization. Studies with Nicotonic Acid," <i>Prog. Biochem. Pharmacol.</i> , 3:151-166 (1967).
	Carlson, L.A., et al., "Effect of a Single Dose of Nicotinic Acid on Plasma Lipids in Patients with Hyperlipoproteinemia," <i>Acta Med. Scand.</i> , 183:457-465 (1968).
	Carlson, L.A., et al., "Plasma Lipids and Urinary Excretion of Catecholamines in Man during Experimentally Induced Emotional Stress, and Their Modification by Nicotinic Acid," <i>J. Clin. Invest.</i> , 47:1795-1805 (1968).
	Carlson, L.A., et al., "Pronounced Lowering of Serum Levels of Lipoprotein Lp(a) in Hyperlipidaemic Subjects Treated with Nicotinic Acid," <i>J. Int. Med.</i> , 226(5):271-276 (1989).
	Cayen, M.N., "Metabolic Disposition of Antihyperlipidemic Agents in Man and Laboratory Animals," <i>Drug Metab. Rev.</i> , 11(2):291-323 (1980).
	Cayen, M.N., et al., "Effect of AY-25,712 on Fatty Acid Metabolism in Rats," <i>Arteriosclerosis</i> 45(3):281-290 (1982).
	Chandler, W.L., et al., "Insulin, Cortisol and Catecholamines Do Not Regulate Circadian Variations in Fibrinolytic Activity," <i>Thrombosis Res.</i> , 58(1):1-12 (1990).
	Chowhan, Z.T., et al., "Hardness Increase Induced by Partial Moisture Loss in Compressed Tablets and Its Effect on <i>In Vitro</i> Dissolution," <i>J. Pharm. Sci.</i> , 67(10):1385-1389 (1978).
	Chowhan, Z.T., "Role of Binders in Moisture-Induced Hardness Increase in Compressed Tablets and Its Effect on <i>In Vitro</i> Disintegration and Dissolution," <i>J. Pharm. Sci.</i> , 69(1):1-3 (1980).
	Chowhan, Z.T., et al., "Compression Properties of Granulations Made with Binders Containing Different Moisture Contents," <i>J. Pharm. Sci.</i> , 70(1):1134-1139 (1981).
	Christensen, N.A., et al., "Nicotinic Acid Treatment of Hypercholesteremia, Comparison of Plain and Sustained-Action Preparation and Report of Two Cases of Jaundice" <i>JAMA</i> , 177(8):76-80 (1961).
	Cooper, K.H., "The Wisdom and Risk of Drug and Vitamin Therapy," <i>Dr. Kenneth H. Cooper's Preventive Medicine Program, Controlling Cholesterol</i> , 244-252, Bantam Books (1988).
	Criscuoli, M., et al., "Glunicate (LG 13979) Protects the Arterial Wall from Cholesterol-Induced Atherosclerotic Changes in the Rabbit Without Affecting Plasma Lipids," <i>Atherosclerosis</i> , 53(1):59-68 (1984).

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b>  <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 15

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

EXAMINER INITIAL	
	Dalton, T.A., et al., "Hepatotoxicity Associated with Sustained-Release Niacin," <i>Am. J. Med.</i> , 93:102-104 (1992).
	Davis, S.S., et al., <i>Modern Concepts in Nitrate Delivery Systems</i> , 30-37, (Eds. A.A.J. Goldberg, D.G. Parsons), 1983 Royal Soc. of Med. Int'l. Congress & Symp. Series No. 54, published jointly by Academic Press Inc. (London) Ltd. and Royal Society of Medicine.
	Dow, "Formulating for Controlled Release with METHOCEL Premium Cellulose Ethers," Dow Chemical Company publications, 1-33 (1995).
	Dow, "METHOCEL as a Binding Agent for Tablet production by Wet Granulation," Dow Chemical Company publication, 1-15 (1985).
	Dow, "Viscosity: Molecular Weight-Viscosity Relationship," Handbook on METHOCEL* Cellulose Ether Products, Dow Chemical Company publication (1974).
	Dow, "Technical Information: Methods of Formulating Controlled Release Products Outside the Forest Lab Patent US 4,389,393 Claims."
	Dow, "Formulating Sustained Release Pharmaceutical Products with METHOCEL," Dow Chemical Company publication.
	Dow, product designation changes for METHOCEL cellulose ethers, Dow Chemical Company publication (1985) (CZ).
	Dow, product designation changes for METHOCEL cellulose ethers, Dow Chemical Company publication (DG) (1960).
	Ekström-Jodal, B., et al., "Influence of Nicotinic Acid and Pentaerythritoltetranicotinate (Percit <sup>®</sup> , Bofors) on the Cardiac Output in Man," <i>Pharmacologia Clinica</i> , 2:86-89 (1970).
	Etchason, J.A., et al., "Niacin-Induced Hepatitis: A Potential Side Effect with Low-Dose Time-Release Niacin," <i>Mayo Clin. Proc.</i> , 66:23-28 (1991).
	Figge, H.L., et al., "Comparison of Excretion of Nicotinuric Acid After Ingestion of Two Controlled Release Nicotinic Acid Preparations in Man," <i>J. Clin. Pharmacol.</i> , 28:1135-1140 (1988).
	Figge, H.L., et al., "Nicotinic Acid: A Review of Its Clinical Use in the Treatment of Lipid Disorders," <i>Pharmacotherapy</i> , 8(5):287-294 (1988).
	Fleischman, A.I., et al., Low Dose Sustained Release Nicotinic Acid As An Effective Hypo Lipidemic Agent In Man," <i>Fed. Proc.</i> , 34(1):248 (1975).

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.



<b>FORM PTO-1449</b>  <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROU</b> 1615

RECEIVED  
 MAY 05 2003  
 TECH CENTER 16012900

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

EXAMINER INITIAL	
	Gray, D.R., et al. "Efficacy and Safety of Controlled-release Niacin in Dyslipoproteinemic Veterans," <i>Ann. Intern. Med.</i> 121:252-258 (1994).
	Gudsoorkar, V.R., et al., "Influence of Binders on Some Physical Parameters of Lactose and Sulfadimidine Tablets," <i>Indian Drugs &amp; Pharmaceuticals Industry</i> , 3-4 (Jul.-Aug. 1980).
	Hamsten, A., et al., "Increased Plasma Levels of a Rapid Inhibitor of Tissue Plasminogen Activator in Young Survivors of Myocardial Infarction," <i>N. Engl. J. Med.</i> , 313(25):1557-1563 (1985).
	Henkin, Y., et al., "Rechallenge With Crystalline Niacin After Drug-Induced Hepatitis From Sustained-Release Niacin," <i>JAMA</i> , 264(2):241-243 (1990).
	Henkin, Y., et al., "Niacin Revisited: Clinical Observations on an Important but Underutilized Drug," <i>Am. J. Med.</i> , 91:239-246 (1991).
	Hodis, H.N., "Acute Hepatic Failure Associated With the Use of Low-Dose Sustained-Release Niacin," Letter to the Editors, <i>JAMA</i> , 264(2):181 (1990).
	Huber, H.E., et al., "Utilization of Hydrophilic Gums for the Control of Drug Release from Tablet Formulations I. Disintegration and Dissolution Behavior," <i>J. Pharm. Sci.</i> , 55(9):974-976 (1966).
	Ibrahim, S.A., et al., "Release Characteristics of Oxyphenbutazone from Different Suppository Bases," <i>Pharmazie</i> , 35(8):567 (1980).
	Jacobson, T.A., et al., "Combination Therapy with Fluvastatin and Niacin in Hypercholesterolemia: A Preliminary Report on Safety," <i>Am. J. Cardiol.</i> , 73:25D-29D (1994).
	Kane, J.P., et al., "Normalization of Low-Density-Lipoprotein Levels in Heterozygous Familial Hypercholesterolemia with a Combined Drug Regimen," <i>N. Engl. J. Med.</i> , 304(5):251-258 (1981).
	Kassem, A.A., et al., "Enhancement of Release Rate of Spironolactone from Its Tablets by the Formation of Solid Dispersions with Water-Soluble Polymers," <i>Jami et Al-Qahira, Faculty of Pharmacy, Cairo University, Bulletin, Cairo</i> , 19(1):275-306 (1980).
	Keenan, J. M., et al., "Niacin Revisited: A Randomized, Controlled Trial of Wax-Matrix Sustained-Release Niacin in Hypercholesterolemia," <i>JAMA Spec. J. Abst.</i> , 266(16):2209 (1991).
	Keenan, J.M., et al., "Niacin Revisited A Randomized, Controlled Trial of Wax-Matrix Sustained-Release Niacin in Hypercholesterolemia," <i>Arch. Intern. Med.</i> , 151:1424-1432 (1991).
	Keenan, J.M., et al., "Treatment of Hypercholesterolemia: Comparison of Younger versus Older Patients Using Wax-Matrix Sustained-Release Niacin," <i>J. Am. Geriat. Soc.</i> , 40:12-18 (1992).

**EXAMINER****DATE CONSIDERED**

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b> <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 16

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

EXAMINER INITIAL	
	King, R.E., "Tablets, Capsules, and Pills," <i>Remington's Pharm. Sci.</i> , 1576-1587 (1975).
	Kirschstein, W., et al., "Impaired Fibrinolytic Capacity and Tissue Plasminogen Activator Release in Patents with Restenosis after Percutaneous Transluminal Coronary Angioplasty (PTCA)," <i>Thromb. Haemost.</i> , 62(2):772-775 (1989).
	Knopp, R.H., et al., "Contrasting Effects of Unmodified and Time-Release Forms of Niacin on Lipoproteins in Hyperlipidemic Subjects: Clues to Mechanism of Action of Niacin," <i>Metabolism</i> , 34(7):642-650 (1985).
	Korsmeyer, R.W., et al., "Mechanisms of Potassium Chloride Release from Compressed, Hydrophilic, Polymeric Matrices: Effect of Entrapped Air," <i>J. Pharm. Sci.</i> , 72(10):1189-1191 (1983).
	Kowalski, R.E., <i>The 8-Week Cholesterol Cure</i> , Harper & Row, Publishers, 95-115 (1989).
	Kruse, W., et al., "Nocturnal Inhibition of Lipolysis in Man by Nicotinic Acid and Derivatives," <i>Eur. J. Clin. Pharmacol.</i> , 16:11-15 (1979).
	Krycer, I., et al., "An Evaluation of Tablet Binding Agents Part I. Solution Binders," <i>Powder Technol.</i> , 34:39-51 (1983).
	Laguna, O., et al., "Enrobage. III. Influence de quelques produits filmogènes et plastifiants sur la dissolution de comprimés à base de chlorure de sodium," ("Coatings. III. Influence of various filmogenic products and plasticizers on the dissolution of tablets with a sodium chloride base") <i>Ann. Pharma. Franc.</i> , 33(5):235-242 (1975). This document relates to the dissolution properties of sodium chloride-based tablets coated with filmogenic products and plasticizers.
	Lapidus, H., et al., "Some Factors Affecting The Release of a Water-Soluble Drug from a Compressed Hydrophilic Matrix," <i>J. Pharm. Sci.</i> , 55(8):840-843 (1966).
	Lapidus, H., "Drug Release from Compressed Hydrophilic Matrices," <i>University Microfilms International</i> , Thesis, Rutgers University, 1-117 (1967).
	Lapidus, H., <i>Chemistry, Abstract</i> , (order No. 67-14,728) 2363-B2364-B (1967).
	Lapidus, H., et al., "Drug Release From Compressed Hydrophilic Matrices," <i>J. Pharm. Sci.</i> , 57(8):1292-1301 (1968).
	Leiner, P., <i>Chain Drug Review Publication</i> , 12 (Jun. 6, 1988).
	Luria, M.H., "Effect of Low-Dose Niacin on High-Density Lipoprotein Cholesterol and Total Cholesterol/High-Density Lipoprotein Cholesterol Ratio," <i>Arch. Intern. Med.</i> , 148:2493-2495 (1988).

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b>  <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 16

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

EXAMINER INITIAL	
	Mahl, M., et al., "A Long Term Study of the Effect of Nicotinic Acid Medication on Hypercholesteremia," <i>Am. J. Med. Sci.</i> , 64:673-677 (1963).
	Malkowska, S., et al., "Effect of Re-Compression on the Properties of Tablets Prepared by Moist Granulation," <i>Drug Dev. Indust. Pharmacy</i> , Marcel Dekker, Inc., 9(3):349-361 (1983).
	Manninen, M., et al., "Lipid Alterations and Decline in the Incidence of Coronary Heart Disease in the Helsinki Heart Study," <i>JAMA</i> , 260(5):641-651 (1988).
	Merck & Co. Inc., The Merck Index, Tenth Ed., 809, 520, 351, 466 (1983).
	Miettinen, T.A., "Diurnal Variation of LDL and HDL Cholesterol," <i>Ann. Clin. Res.</i> , 12:295-298 (1980).
	Miettinen, T.A., "Cholesterol Precursors and Their Diurnal Rhythm in Lipoproteins of Patients with Jejuno-Ileal Bypass and Ileal Dysfunction," <i>Metabolism</i> , 34(5):425-430 (May 1985).
	Miettinen, T.A. "Diurnal Variation of Cholesterol Precursors Squalene and Methyl Sterols in Human Plasma Lipoproteins," <i>J. Lipid Res.</i> , 23:466-473 (1982).
	Miettinen, T.A., "Detection of Changes in Human Cholesterol Metabolism," <i>Ann. Clin. Res.</i> , 2:300-320 (1970).
	Miller, O.N., et al., "Investigation of the Mechanism of Action of Nicotinic Acid on Serum Lipid Levels in Man," <i>Am. J. Clin. Nutr.</i> , 8:480-490 (1960).
	Muller, J.E. et al., "Circadian Variation in the Frequency of Sudden Cardiac Death," <i>Circulation</i> , 75:131-138 (1987).
	Nagy, G. et al., "Untersuchungen über die Textur und die Eigenschaften von Acetylsalicylsäure-Tabletten 1. Mitteilung: Ein Fluß der Herstellung-sweise auf die Eigenschaften der Tabletten," ("The texture and properties of acetylsalicylic acid tablets. 1. The effect of manufacturing methods on the properties of tablets") <i>Pharmazie</i> , 33(1):747-749 (1978). This document relates to the effect of manufacturing methods on the properties and textures of acetylsalicylic acid tablets.
	Neuvonen, P.J., et al., "The Bioavailability of Sustained Release Nicotinic Acid Formulations," <i>Br. J. Clin. Pharmacol.</i> , 32:473-476 (1991).
	Pinter, E.J. et al., "Biphasic Nature of Blood Glucose and Free Fatty Acid Changes Following Intravenous Nicotinic Acid in Man," <i>J. Clin. Endocrinol. Metab.</i> , 27:440-443 (1967).

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449</b>  <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

EXAMINER INITIAL	
	Pintye-Hodi, K., et al., Untersuchungen über die Textur und die Eigenschaften von Acetylsalicylsäure-Tabletten 2. Mitteilung: Untersuchung der Textur durch Feuchtgranulierung bereiteter Tabletten," <i>Pharmazie</i> , 35(3):168-170 (1980) (with English translation of Abstract attached).
	Rader, J.I., et al., "Hepatic Toxicity of Unmodified and Time-Release Preparations of Niacin," <i>Am. J. Med.</i> , 92:77-81 (1992).
	Remington's Pharmaceutical Sciences, 15 <sup>th</sup> Ed., 1242-1251, Mack Publishing Co., Easton, PA. (1975).
	Remington's Pharmaceutical Sciences, 18 <sup>th</sup> Ed., 1636-1637, Mack Publishing Co., Easton, PA (1990).
	Remington's Pharmaceutical Sciences, 1304-1323; 1676-1686, Mack Publishing Co., Easton, PA, (1990).
	Renzetti, A.R., et al., "Further Assessment of Glunicate Hypolipidaemic Activity in the Rat," <i>J. Pharm. Pharmacol.</i> , 37(12):906-909 (1985).
	Ross, R., "The Pathogenesis of Atherosclerosis-An Update," <i>N. Engl. J. Med.</i> , 314(8):488-500 (1986).
	Rowland, M., et al., <i>Clinical Pharmacokinetics: Concepts and Applications</i> , Les & Feiger, 111 (1980).
	Salomon, J-L., et al., "Importance de la technologie et de la formulation pour le mécanisme de libération du chlorure de potassium contenu dans des matrices hydrophiles 1. Influence de la viscosité et du pourcentage de gélifiant," ("Importance of technology and formulation for the mechanism of continuous liberation of potassium chloride from hydrophilic matrices. 1. Effect of viscosity and percentage of excipient") <i>Pharm. ACTA Helv.</i> , 54(3):82-85 (1979) (with English translation of Abstract).
	Salomon, J-L., et al., "Sustained Release of a Water-Soluble Drug from Hydrophilic Compressed Dosage Forms," <i>Pharm. Ind.</i> , 41(8):799-802 (1979).
	Schlierf, G., et al., "Diurnal Patterns of Triglycerides, Free Fatty Acids, Blood Sugar, and Insulin During Carbohydrate-Induction in Man and Their Modification by Nocturnal Suppression of Lipolysis," <i>J. Clin. Invest.</i> , 52:732-740 (1973).
	Schlierf, G., et al., "Inhibition of Carbohydrate-Induced Hypertriglyceridemia by Nicotinic Acid," <i>Artery</i> , 3(2):174-179 (1977).
	Schlierf, G., et al., "Diurnal Patterns of Plasma Triglycerides and Free Fatty Acids in Normal Subjects and in Patients with Endogenous (Type IV) Hyperlipoproteinemia," <i>Nutr. Metabol.</i> , 13:80-91 (1971).

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

RECEIVED

MAY 05 2003

TECH CENTER 1600/2900

<b>FORM PTO-1449</b>  <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 20720-95585	<b>APPLN. NO.</b> 08/962,027
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

EXAMINER INITIAL	
	Schlierf, G., et al., "Modification of 'Carbohydrate-Induced' Triglyceridemia by Nocturnal Suppression of Lipolysis – Comparison of Nicotinic Acid and Glucose," <i>Pharmacological Control of Lipid Metabolism, Proceedings of the Fourth International Symposium on Drugs Affecting Lipid Metabolism, Philadelphia, PA</i> , 26:319-320 (1971).
	Schulman, K.A., et al., "Reducing High Blood Cholesterol Level With Drugs – Cost-effectiveness of Pharmacologic Management," <i>JAMA</i> , 264(23):3025-3033 (1990).
	Shepherd, J., et al., "Effects of Nicotinic Acid Therapy on Plasma High Density Lipoprotein Subfraction Distribution and Composition and on Apolipoprotein A Metabolism," <i>J. Clin. Invest.</i> , 63:858-867 (1979).
	Sokoloski, T.T., "Solutions and Phase Equilibria," <i>Remington's Pharmaceutical Sciences</i> , 17 <sup>th</sup> Ed., 207-208, Mack Publishing Co., Easton, PA (1985).
	Sprengers, E.D., et al., "Plasminogen Activator Inhibitors" <i>Blood</i> , 69(2):381-387 (1987).
	Squires, R.W., et al., "Low-Dose, Time-Release Nicotinic Acid: Effects in Selected Patients With Low Concentrations of High-Density Lipoprotein Cholesterol," <i>Mayo Clin. Proc.</i> , 67(9):855-860 (1992).
	Subissi, A., et al., "Acute Effects on Plasma Lipids in the Rat of a New Long-Acting Nicotinic Acid Derivative: LG 13979," <i>J. Pharm. Pharmacol.</i> 35:571-575 (1983).
	Svedmyr, N., et al., "The Relationship between the Plasma Concentration of Free Nicotinic Acid and Some of Its Pharmacologic Effects in Man," <i>Clin. Pharm. Ther.</i> , 4(10):559-570 (1969).
	Urberg, M., et al., "Evidence for Synergism Between Chromium and Nicotinic Acid in the Control of Glucose Tolerance in Elderly Humans," <i>Metabolism</i> , 36(9):896-899 (1987).
	Urburg, M., et al., "Hypocholesterolemic Effects of Nicotinic Acid and Chromium Supplementation," <i>J. Family Practice</i> , 27(6):603-606 (1988).
	Wahlberg, G., et al., "Effects of Nicotinic Acid on Concentrations of Serum Apolipoproteins B, C-I, C-II, C-III and E in Hyperlipidemic Patients," <i>Acta Med. Scand.</i> , 224:319-327 (1988).
	Wiman, B., et al., "The Role of the Fibrinolytic System in Deep Vein Thrombosis," <i>J. Lab. Clin. Med.</i> , 105(2):265-270 (1985).
	Complaint, filed by Kos Pharmaceuticals, Inc. against Barr Laboratories on March 4, 2002, in Civil Action No. 02 CV 1683.
	First Amended Complaint, filed by Kos Pharmaceuticals, Inc. on March 11, 2002, in Civil Action No. 02 CV 1683.

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

RECEIVED

MAY 05 2003

FCH CENTER 1600/2909

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.  
20720-95585APPLN. NO.  
08/962,027INFORMATION DISCLOSURE  
STATEMENT BY APPLICANTAPPLICANT  
Eugenio A. CefaliCONFIRMATION  
NO.FILING DATE  
October 31, 1997GROSS  
1615RECEIVED  
MAY 05 2003  
TECH CENTER 16001200

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
	Answer To First Amended Complaint, filed by Barr Laboratories on March 25, 2002, in Civil Action No. 02 CV 1683.
	Reply To Counterclaims, filed by Kos Pharmaceuticals, Inc. on April 15, 2002, in Civil Action No. 02 CV 1683.
	Amended Answer To First Amended Complaint, filed by Barr Laboratories on August 19, 2002, in Civil Action No. 02 CV 1683.
	Complaint, filed by Kos Pharmaceuticals, Inc. on August 13, 2002, in Civil Action No. 02 CV 6409.
	Answer To Complaint, filed by Barr Laboratories on September 3, 2002, in Civil Action No. 02 CV 6409.
	Complaint, filed by Kos Pharmaceuticals, Inc. on November 12, 2002, in Civil Action No. 02 CV 8995.
	Answer To Complaint, filed by Barr Laboratories on December 3, 2002, in Civil Action No. 02 CV 8995.
	Reply To Counterclaims And Counterclaims For Declaratory Judgment, filed by Kos Pharmaceuticals, Inc. on March 4, 2003 in Civil Action No. 02 CV 8995.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.